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TRANSMITTAL FORM

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Total Number of Pages in This Submission

10

Application Number 10/539,842

Filing Date June 20, 2005

First Named Inventor MUNTAU-HEGER

Art Unit 1614

Examiner Name VAKILI, Zohreh

Attorney Docket Number 3535.020

ENCLOSURES (Check all that apply)

- ☐ Fee Transmittal Form
☐ Fee Attached
☐ Amendment/Reply
☐ After Final
☐ Affidavits/declaration(s)
☐ Extension of Time Request
☐ Express Abandonment Request
☒ Information Disclosure Statement

- ☐ Certified Copy of Priority Document(s)
☐ Reply to Missing Parts/
Incomplete Application
☐ Reply to Missing Parts
under 37 CFR 1.52 or 1.53

- ☐ Drawing(s)
☐ Licensing-related Papers
☐ Petition
☐ Petition to Convert to a
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- ☐ After Allowance Communication to TC
☐ Appeal Communication to Board
of Appeals and Interferences
☐ Appeal Communication to TC
(Appeal Notice, Brief, Reply Brief)
☐ Proprietary Information
☐ Status Letter
☒ Other Enclosure(s) (please identify
below):

Forms PTO/SB/08A & PTO/SB/08B; copies
of foreign and non-patent literature
documents; return postcard.

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Akerman Senterfitt		
Signature	<i>Nicholas J. Landau</i>		
Printed name	Nicholas J. Landau, Ph.D.		
Date	11/02/2006	Reg. No.	57,120

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of MUNTAU-HEGER, *et al.* Confirmation No. 5018

Application No. 10/539,842

Examiner: VAKILI, Zohreh

Filed: June 20, 2005

Group Art Unit: 1614

Attorney Docket No. 3535.020

For: USE OF TETRAHYDROBIOPTERINE DERIVATIVES IN THE TREATMENT
AND NUTRITION OF PATIENTS WITH AMINO ACID METABOLIC DISORDERS

INFORMATION DISCLOSURE STATEMENT

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Nicholas J. Landau, Reg. No. 57,120
Nicholas J. Landau, Ph.D.

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §1.56, Applicants hereby notify the U.S. Patent Office of the documents which are listed on the attached Forms PTO/SB/08A and PTO/SB/08B.

Applicants submit that the present invention is patentable over the cited references and submission of the listed documents is not intended as an admission that such documents constitute prior art against the present application. Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove the listed documents as competent references against the present application.

The below references 2, 3, 9, 12, 13, 19, 22, 28, 31, and 33 were cited in the European Search Report issued in corresponding European application as "Category X," or of particular relevance. The references 2, 3, 6, 13, 19, 21, and 30 were cited in a European Office Action for the corresponding International Application. References 1 – 5, 7, 8, 10, 11, 13 – 15, 17, 18, 20, 23 – 17, 29, and 31 – 33 were cited in a Protest of the U.S. National Phase of International Application no. PCF/EP2003/014262 pursuant to 37 C.F.R. §1.291. Copies of U.S. references are not enclosed. A copy of each foreign language reference is enclosed, along with a English translation of the abstract, where available. A copy of the international search report and European Office Action (in German, as no English translation is available) are also enclosed.

Applicants respectfully request that the listed documents be considered by the Examiner and made of record in the present application and that an initialed copy of forms PTO/SB/08A and PTO/SB/08B be returned in accordance with MPEP §609.

1. U.S. Patent No. 4,774,244
2. U.S. Patent No. 4,778,794
3. U.S. Publication No. 2002/0052374 A1
4. U.S. Patent No. 5,763,392
5. U.S. Patent No. 6,428,990 B1
6. WO 1995/13803
7. BATES, et al., "Children's Medications: A Parent's Guide", page 6, Harvery Whitney Books, Cincinnati, Ohio, (1996).
8. BLAU, et al., "34th EMG Meeting, Zurich CH, held May 31-June 2, 2003", proceedings published October 2002.
9. BERNEGGER, et al., "High frequency of tetrahydrobiopterin-responsiveness among hyperphenylalaninemias...", Molecular Genetics and Metabolism, 77:304-313 (2002).

10. CURTIUS, et al., *The Lancet*, 1:657-658 (March 19,1983).
11. CURTIUS, et al., "Therapeutic Efficacy of Tetrahydrobiopterin in Parkinson's Disease", *Advances in Neurology*, 40:463-466 (1984).
12. CURTIUS, et al., "Atypical Phenylketonuria due to Tetrahydrobiopterin...", Elsevier/North-Holland Biomedical Press, 93:251-252 (1979).
13. DISSING, et al., "Tetrahydrobiopterin and Parkinson's Disease", *Acta Neurol. Scand.*, 79:493-499 (1989).
14. ELLIS, JOHN R., "The general concept of molecular chaperones", *Phil. Trans. R. Soc. Lond. B*, 339:257-261 (1993).
15. ERLANDSEN, et al., "A structural hypothesis for BH4 responsiveness in patients...", *J. Inherit. Metab. Dis.* 24:213-230 (2001).
16. FURUKAWA, et al., "Striatal biopterin and tyrosine hydroxylase protein reduction dopa-responsive dystonia", *Neurology*, 53:1032-1041 (1999).
17. HENNERMANN, et al., "Partial and Total Tetrahydrobiopterin-responsiveness in classical and mild phenylketonuria (PKU)", *J. Inherit. Metab. Dis., Suppl.* 1:1-184 (2002).
18. ISAACS, JOHN, "Helping the Medicine Go Down", *American Druggist*, 37-41 (1999).
19. KITAGAWA, et al., "A Nation-wide Study of Tetrahydrobiopterin- responsive Phenylalanine...", *J. Inherit. Metab. Dis. Suppl.* 1: 24 (2001).
20. KURE, et al., "Tetrahydrobiopterin-responsive phenylalanine hydroxylase deficiency", *The Journal of Pediatrics*, 135:375-8 (1999).
21. MILLER, et al., "Role of Hydroxylase Cofactor in Regulating Dopamine Synthesis: Relevance to Neurological Disorders", 471-474 (1986).
22. MUNTAU, et al., "Tetrahydrobiopterin as an Alternative Treatment for Mild Phenylketonuria", *N Engl J Med*, 347-26:2122-32 (2002).

23. NAGATSU, TOSHIHARU, "Tyrosine hydroxylase: human isoforms, structure and regulation in physiology and pathology", *Essays in Biochemistry*, 30:15-35 (1995).
24. "PhenylAde", Product Guide, Applided Nutrition Corp., (November 2002).
25. "PhenylAde", Product Guide, Applided Nutrition Corp., (May 2002).
26. SCHAUB, et al., "Tetrahydrobiopterin therapy of atypical phenylketonuria due to defective dihydrobiopterin biosynthesis", *Archives of Disease in Childhood*, 53:674-683 (1978).
27. SHINOZAKI, et al., "Oral Administration of Tetrahydrobiopterin Prevents Endothelial Dysfunction..." *Circulation Research*, 87:655-73 (2000).
28. STEINFELD, et al., "A hypothesis on the biochemical mechanism of BH4-responsiveness in phenylalanine hydroxylase deficiency", *Amino Acids*, 25:63-68 (2003).
29. STEINFELD, et al., "Tetrahydrobiopterin monotherapy for phenylketonuria patients with common mild mutations", *Eur J Pediatr*, 161:403-5 (2002).
30. TANAKA, et al., "On-off phenomenon in a child with Tetrahydrobiopterin deficiency due to 6-pyruvoyl tetrahydropterin synthase...", *Eur J Pediatr*, 148:450-52 (1989).
31. TREFZ, et al., "Successful treatment of phenylketonuria with tetrahydrobiopterin", *Eur J. Pediatr*, 160:315 (2001).
32. WALTER, et al., "Inhalation of the Nitric Oxide Synthase Cofactor Tetrahydrobiopterin in Health Volunteers", *Am J Respir Crit Care Med*, 156: 2008-10 (1997).
33. WEGLAGE, et al., "Tetrahydrobiopterin responsiveness in a large series of phenylketonuria patients", *J. Inherit. Metab. Dis.* 25:321-322 (2002).

Certification

This Statement is being filed prior to the issuance of the first Office Action for the present application, and this paper is thus submitted in accordance with 37 C.F.R. 1.97(b).

In view of the above certification, a fee is not required for consideration of this document. Nevertheless, should a fee be deemed to be due by the Commissioner, such fee should be charged to Deposit Account No. 50-0951.

Respectfully submitted,

Dated: 11/02/2006

Nicholas J. Landau
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Docket No. 3535.020



PTO/SB/08A (09-06)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

Application Number 10/539,842
Filing Date June 20, 2005
First Named Inventor MUNTAU-HEGER
Art Unit 1614
Examiner Name VAKILI, Zohreh
Attorney Docket Number 3535.020

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
[Z.V.] ↓		US- 4,774,244	09-27-1988	CURTIS, ET AL	
		US- 4,778,794	10-18-1988	NARUSE, ET AL	
		US- 2002/0052374 A1	05-02-2002	RABELINK, ET AL	
		US- 5,763,392	06-09-1998	HANSEN, ET AL	
		US- 6,428,990 B1	08-06-2002	MUKERJI, ET AL	
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FOREIGN PATENT DOCUMENTS

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[Z.V.]		Country Code* Number** Kind Code* (if known) WO 1995/13803	05-26-1995	CORNELL RESEARCH		

Examiner Signature	[Zohreh Vakili]	Date Considered	04/06/2009
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*EXAMINER Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * Applicant's unique citation designation number (optional). * See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. * Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). * For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. * Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. * Applicant is to place a check mark here if English language Translation is attached.
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Attorney Docket Number	3535.020

Sheet 2 of 4

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/Z.V./		BATES, et al., "Children's Medications: A Parent's Guide", page 6, Harvery Whitney Books, Cincinnati, Ohio, (1996).	
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Examiner Signature	/Zohreh Vakili/	Date Considered	04/06/2009
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Examiner Signature	/Zohreh Vakili/	Date Considered	04/06/2009
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Sheet 4

of

4

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Examiner Signature	/Zohreh Vakili/	Date Considered	04/06/2009
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